REMARKS/ARGUMENTS

Claims 1-46 and 57-67 were pending in this application when last Examined by the Examiner. Claims 1-46 and 57-67 have been cancelled. Claims 76-89 have been added. The amendments find support in the original specification, claims, and drawings. No new matter has been added. This amendment is being submitted with a Request for Continued Examination. Entry of the above amendments and an early indication of allowance of the now pending claims 76-89 are respectfully requested.

Claim Rejections under 35 U.S.C. § 101

Claims 1-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 57-66 are rejected under 35 U.S.C. 101 because the claimed invention is abstract, lacks utility, and violates the doctrine of preemption.

Claims 1-46 and 57-66 have been canceled in favor of new claims 76-89. New independent claims 76 and 83 provide a method and system, respectively, for data mining, that determines a plurality of emerging patterns that are configured to be used to determine whether a test cell is normal or diseased. Applicants submit that the determination of these emerging patterns to produce a diagnostic indicator of normal or diseased cells is useful, concrete and tangible, and therefore provides patentable subject matter.

In the previous subject matter rejections, the Examiner states, with respect to previous claims 34 and 35, that "classifying a cell type as cancerous or non-cancerous is not a substantial and specific result, because the terms cancerous and non-cancerous are mathematical abstractions derived from data modeling." Applicants respectfully disagree. The vast majority of current medical tests provide only a probability that a test sample is either normal or diseased. These tests will still provide the occasional positive result (diseased) when applied to a normal cell, and the occasional negative result (normal) when applied to a diseased cell. However, the results remain both substantial and useful, as they are routinely applied by diagnosticians to make such determinations. The fact that the tests are not 100% reliable does not mean that they

do not provide a substantial and specific result. Applicants believe that the lists created by the method of new claim 76 are at least as concrete a diagnostic tool as the measurement of a blood sugar level obtained through statistical methods for diagnostic purposes. Applicants note that all blood sugar measurement systems depend on a statistical sampling process. Specifically, there is no test of which applicants are aware that actually distills a blood sample to physically measure the amount of sugar contained therein. Withdrawal of the rejection under 35 U.S.C. 101 is therefore respectfully requested.

Claim Rejections under 35 U.S.C § 102 and 35 U.S.C. § 103

Claims 1, 11, and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Wang et al., "Monitoring gene expression profile changes in ovarian carcinomas using cDNA microarray," 1999 (the Wang reference). Claim 57 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wang in view of Sheppard (U.S. Patent No. 6,026,397).

Claims 1-46 and 57-66 have now been canceled. Accordingly, Applicant will address the Examiner's rejections with respect to new claims 76-89.

In rejecting claims 1, 11, and 67 based on the Wang reference, the Examiner interprets "normal and neoplastic ovary" disclosed in the Wang reference as two classes of data. Assuming, *arguendo*, that neopolastic qualifies as "diseased" for the purposes of independent claim 76, the Wang reference still fails to teach or suggest a method for determining emerging patterns with all the other limitations recited in claim 76. For example, Wang fails to teach or suggest a "training data set D containing gene expression data for a plurality of genes derived from a normal cell group including a plurality of normal cells and a diseased cell group including a plurality of diseased cells." The Examiner contends that Wang's training data set comprises the "seven different ovarian tumor specimens" that has at least one instance of each of said n classes. However, the seven different ovarian tumor specimens disclosed in Wang are all drawn from a single class, namely, the diseased class. No normal class of data is represented by these specimens. Thus, claim 76 is in condition for allowance for this reason alone.

The Examiner also states that the gene expression level is a variable, and a "3-fold or greater change" is a constraint. Applicant respectfully disagrees. A "3-fold or greater change" is not a constraint, but rather, another variable. The value depends on an expression level in a normal cell multiplied by three or more to arrive at the expression level in a diseased cell. Furthermore, it is impossible to use this value as a constraint, given that the interpretation of the training data set provided by the Examiner does not include data from normal cells. There is no basis under the Examiner's interpretation on which to calculate "fold."

In contrast, claim 76 recites that the claimed "condition" is based on "a fixed range of said gene expression data for at least one of said plurality of genes." This limitation is not taught nor suggested by the Wang reference. As noted above, any constraint based on the concept of "fold" is, by definition, variable. Accordingly, claim 76 also is in condition for allowance for this additional reason.

New independent claim 83 includes limitations that are similar to the limitations of claim 76 which makes claim 76 allowable. Accordingly, claim 83 is in condition for allowance.

Claims 77-82 and 84-89 are also in condition for allowance because they depend on an allowable base claim, and for the additional limitations that they contain. Specifically with respect to claims 77 and 84, these claims add the limitation that "at least one of said emerging patterns from the training data set D comprises at least three conditions for each of said normal and diseased cells." This is not disclosed in the Wang reference. Accordingly, claims 77 and 84 are also in condition for allowance for this added limitation.

Claims 79 and 86 provide, inter alia, applying "an entropy based discretization technique to said training data set, to generate a cut point that defines said fixed range, such that said normal data falls within said fixed range on one side of said cut point, and said diseased data falls on an opposite side of said cut point." This limitation is also not discussed anywhere in the Wang reference. Accordingly, claims 79 and 86 are also in condition for allowance for this added limitation.

To assist the Examiner in understanding the powerful nature of the emerging patterns method and system as claimed in claims 76 and 83, Applicant believes that a further discussion

of the specific results obtained in applying the technique may be useful. Applicant thus refers the Examiner to Example 2, on pages 52-66 of the specification.

Table D on pages 54-55 illustrates the results obtained from the discretization step performed in claims 79 and 86. Each of the identified genes and corresponding intervals provides a statistically significant indicator as to whether or not a cell is normal or diseased. While these genes and intervals can be very useful when applied singly, the emerging pattern approach provides an aggregate of the indicators (emerging patterns) that become even more statistically significant to produce the diagnostic test of claim 76.

Table E illustrates some of the emerging patterns identified, and their respective frequencies of occurrence, calculated as per claims 76 and 83. Note that the top ten emerging patterns that occur at least 90% of the time in normal cells, but not at all in diseased cells, include at least 6 conditions. Similarly, the top few emerging patterns that occur in at least 60% of the diseased cells, but not at all in the normal cells, include 2 to 4 conditions. It is the ability to identify these conditions as claimed in the currently pending claims that makes the claimed emerging pattern approach both novel and inventive over the prior art.

In view of the above amendments and remarks, Applicant respectfully requests reconsideration and an early indication of allowance of the now pending claims 76-89.

Respectfully submitted,
CHRISTIE, PARKER & HALE, LLP

By _____
Josephine E. Chang
Reg. No. 46,083
626/795-9900

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